DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
M2650M

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

January 29, 1999

WARNING LETTER
CHI-8-99

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John R. Franz, President & CEO
KaVo America Company
340 East Main Street
Lake Zurich, IL 60047

Dear Mr. Franz:

During an inspection of your firm from August 17, 18, 25 to September 1, 1998, Chicago District Investigator Norman Brown and Leslie Dorsey from the Center for Devices and Radiological Health, Office of Compliance, determined that your firm is a manufacturer of steam autoclaves and dental handpieces. The products that your firm manufactures are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for the manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR) for Medical Devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish and maintain procedures to ensure that the device history records for each unit are maintained to demonstrate that the device is manufactured in accordance with the device master record. The device history record shall include or refer to the location of:

   a) The acceptance records which demonstrate the device is manufactured in accordance with the device master record; and

   b) Any device identification(s) and control number(s) used. Serial numbers of reworked dental handpieces are not recorded on your "Operation Sheets".

Our investigation found your firm uses "Operations Sheets" to capture various in-process test results. [redacted] "Operation Sheets" dated August 5-12, 1998, were reviewed and found incomplete due to missing test results. Also, when dental handpieces were reworked, the "Operations Sheets" did not contain documentation of the serial numbers of the devices.

2. Your complaint handling procedure, "Processing customer complaints," does not ensure that :

   a) All oral complaints are documented upon receipt. 21 CFR Part 820.3 defines a complaint as "...any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution." Any complaint suggesting the possible failure of the device to meet any of its specifications shall be reviewed, evaluated, and investigated;

   b) When an investigation is made a record of the investigation shall be maintained. The investigation records shall include: the device name; date the complaint was received; serial number of the device; complainant information including name, address, and phone number; details of the complaint, dates and results of the investigation; corrective action taken; and any reply to the complainant; and

   c) When no investigation is made, the record of the investigation shall include the reason no investigation was initiated, and the name of the individual who made the decision not to investigate.

Our investigation found your firm received telephone calls from customers who reported that handpieces flew apart and/or parts fell off of the handpieces, while the devices were being used on patients. These complaints were handled as service requests or telephone inquiries. Some of the complaints were informally documented as telephone notes. Others were documented on service records. These records did not contain documentation of an investigation, or the reason no investigation was made, corrective actions taken, and/or reply to the complainant.

3. The Quality System Regulation requires manufacturers designate an individual(s) to review for adequacy, and approve prior to issuance, all documents established to meet the requirements of the Quality System Regulation. That approval shall include the date and signature of the official(s) approving the document.

Our investigation found the test instructions for KaVo turbines 634P, 635B, 642B/643B, and 647B, all dated June 17, 1998, did not include a documented approval signature and date.

4. Your process controls do not include documented instructions, standard operating procedures (SOPs), and methods that define and control all manners of production.

Our investigation found no written procedures for the addition of the setscrews to the heads of model 642 handpieces. Also there were no written procedures for the sterilization of handpieces following servicing.

The KaVo steam autoclave is adulterated under Section 501(f)(1)(B) of the Act because it is considered to be a Class III device under Section 513(f), which is not exempt under 520(g), and is required to have in effect an approved application for premarket approval, and no such approval is in effect for it.

The KaVo steam autoclave is also misbranded within the meaning of Section 502(o) in that a notice or other information respecting the devices has not been provided to the FDA as required by 21 CFR 807.81(a)(3)(ii) for new intended uses such as sterilization of dental handpieces.

This letter is not intended as an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 (enclosed) issued to Douglas E. Cochrane, Product Manager, at the closeout of the inspection, may be symptomatic of serious underlying problems in your firm's quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge receipt of Mr. Cochrane's response to our Form FDA 483, dated September 3, 1998. In that response, he proposed a timeline for completing the corrective actions. We will verify these corrections during the next inspection of your facility.

We also want to acknowledge receipt of documents provided as a result of our September 25, 1998 meeting with you at the Chicago District office.

Until FDA has documentation to establish that all corrections have been made, Federal agencies will be advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter regarding the specific steps you have taken to correct the above violations. Include an explanation of each step being taken to ensure all future safety notifications issued by the foreign device manufacturers will be communicated to your office.

Your response should be sent to Richard Harrison, Acting Director, Compliance Branch, Food and Drug Administration, 300 South Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Sincerely,

/s/
Raymond V. Mlecko
District Director

Enclosure

cc: Mr. Jurgen Holfmeister, President
Kaltenback & Voigt & Co KG GmbH
Bismarckring 39
88396 Biberach An Der Riss
Germany